

REMARKS

Claims 1-23 are pending in the application. The claims can be divided into the following three embodiments:

- (A) Claim 1-8 and 21-23 of the present application are directed to a method for treating infection in a patient having an infection (i.e., an infectious disease), which is not HIV.
- (B) Claim 9-14 and 21-23 of the present application are directed a method of increasing the number of dendritic cells in a patient having an infection (i.e., an infectious disease), which is not HIV.
- (C) Claim 15-23 of the present application are directed to a method of augmenting immune responses in a patient having an infection (i.e., an infectious disease), which is not HIV.

The Examiner contends that the effective filing date of the present claims is August 19, 2003, i.e., the filing date of U.S. Application No. 10/643,384 (the present application).

Specifically, in paragraph 3, on page 2 of the Office Action, the Examiner states that the present claims are not supported in Grandparent Application No. 09/444,072, because it is the Examiner's position that "infectious disease" may result from a microbial agent that is not limited to a virus or bacteria, i.e., fungi, protozoa, multicellular parasites and prions.

For the following reasons, Applicants respectfully submit that they are entitled to an effective filing date of October 3, 1996, of U.S. Patent Application Serial No. 08/725,540 with respect to the present claims, or at least

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November 19, 1999, the filing date of U.S. Patent Application Serial No. 09/444,072.

The Examiner is requested to note that the present application is a Divisional of pending U.S. Application No. 10/241,927, filed September 10, 2002; which is a Continuation of U.S. Application No. 09/444,027, filed November 19, 1999 (now abandoned). Hence, the effective filing date of the present claims should be at least November 19, 1999.

The present specification, and thus also the specification of U.S. Application No. 10/241,927, and U.S. Application No. 09/444,027, disclose the situation where the antigen, such as a bacterial antigen or viral antigen, may already exist within the patient and that flt3-ligand may be administered as a vaccines adjuvant to enhance an immune response to the viral or bacterial antigen (see, e.g., page 17, lines 10 et seq. thereof). Thus, it is clear that the present specification, as well as the priority specification disclose treatment of infection generally, as the presence of, e.g., the bacterial or viral antigen in the patient would arise as result of the patient being infected with the, e.g., bacteria or virus.

In this regard, the Examiner is requested to note that original Claim 3 of U.S. Application No. 09/444,027 was directed to a method of augmenting an immune response in a patient which "has an infectious disease" (see also, page 4, lines 29 et seq. thereof). Infectious diseases is generic in Claim 3, and result from infection with, e.g., a bacteria or viral (i.e., with any infectious agent).

Similarly, U.S. Application No. 10/241,927 generically teaches a method of augmenting an immune response in a patient

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which "has an infectious disease" (see also, page 4, lines 17 et seq thereof).

The Examiner is further requested that U.S. Application No. 09/444,027, filed November 19, 1999, is a Continuation-In-Part of U.S. Application No. 09/154,903, filed September 17, 1998 (now abandoned); which is a Continuation-In-Part of U.S. Application No. 08/725,540, filed October 3, 1996 (now abandoned).^{1/} Support for the pending claims also can be found in this application.

More specifically, at page 3, line 34 et seq, of U.S. Patent Application No. 08/725,540, it is disclosed that:

The invention also provides a method of augmenting an immune response in a patient that has an infectious disease wherein the method comprises the step of administering an amount of flt3-ligand sufficient to increase the patient's number of dendritic cells...

Further, at page 11, lines 23-28, the of U.S. Patent Application No. 08/725,540 it is disclosed that:

More specifically, the invention provides for the use of an effective amount of flt3-ligand to increase or mobilize dendritic cells in vivo, for example, in the patient's peripheral blood or spleen. By increasing the quantity of the patient's dendritic cells, such cells may themselves be used to present antigen to T cells. For example, the antigen may be one that already exists within the patient, such as a tumor antigen, or a bacterial or viral antigen.

^{1/} U.S. Application No. 08/725,540 is a Continuation-In-Part of U.S. Application No. 08/539,142, filed October 4, 1995 (now abandoned). Applicants also claim benefit of this prior application.

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In addition, original Claim 3 of the U.S. Patent Application Serial No. 08/725,540 recites:

A method for augmenting an immune response in a patient having an infectious disease, comprising the step of administering flt3-ligand in an amount sufficient to generate an increase in the number of the patient's dendritic cells.

Thus, it is clear that a written description for the genus of infectious disease, as well two species of that genus are also described in U.S. Patent Application Serial No. 08/725,540.

Applicants respectfully submit that the Examiner improperly attempts to limit Applicants disclosure on "infectious disease" to that caused by bacteria or virus. The disclosure noted-above is not limited to the recited pathogens of bacteria and viruses, which are simply disclosed as exemplary in the present specification. Thus, the disclosure of the priority applications satisfies the written description requirement.

The Examiner also states that the negative proviso that the infectious disease is "not HIV" is not supported in Grandparent Application No. 09/444,072.

Also, on page 5 of the Office Action, the Examiner contends that the proviso that the infectious disease is "not HIV" constitutes new matter, and rejects Claims 1-23 under 35 U.S.C. § 112, on this basis as set forth on page 6 of the Office Action.

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

Support for the proviso that the infectious disease is not HIV, can be found in U.S. Patent 5,554,512, which was incorporated by reference in its entirety (see, e.g., page 4,

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lines 34-36 of U.S. Patent Application Serial No. 08/725,540), and which discloses that Flt3-L may be used to treat HIV. Thus, this information has been disclosed in Applicants' priority document and Applicants are entitled, as a matter of law, to proviso out information disclosed in said Patent.

More specifically, the law does not require express disclosure in the application to support a proviso (see *In re Johnson and Farnham*, 194 U.S.P.Q. 187 (CCPA 1977); a copy of which is attached hereto). In *Johnson*, the CCPA overturned the Examiner's and the Board's § 112, first paragraph rejection of claims to a class of polymers that were amended to exclude two species. The two species were not excluded in the specification. The Patent Office mistakenly argued that:

the claims at issue contain provisos The artificial subgenus this created in the claims is not described in the parent case and would be new matter *Id.* at 192.

The CCPA did not focus on whether the proviso was supported, but instead looked to see if the amended claim (with the proviso) as a whole satisfied § 112, first paragraph. Following and affirming their decision in *In re Wertheim*, 191 U.S.P.Q. 90, 97 (CCPA 1976), the CCPA held that the twenty-six examples in Johnson's case supported the amended claims, and that the removal of the two species was merely:

the applicant claiming less than the full scope of his disclosure. *In re Johnson and Farnham, Id.* at 195.

Accordingly, Applicants respectfully submit that they are entitled to an effective filing date of at least November 19, 1999, and more particularly, an effective filing date of October 3, 1996. Thus, Applicants request that the

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Examiner acknowledge the same and withdraw the new matter rejection.

In paragraph 6, on page 7 of the Office Action, the Examiner rejects Claims 1-23 under 35 U.S.C. § 102(e) as being anticipated by McKenna et al.

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

As noted above, it is Applicants position that the priority documents do support the present claims. As a result, McKenna et al, which at best has a 102(e) date of November 19, 2002, is not effective prior art, as the present claims have an effective filing date of at least November 19, 1999.

Thus, Applicants request withdrawal of the Examiner's rejection.

In paragraph 7, on page 8 of the Office Action, the Examiner rejects Claims 1-23 under 35 U.S.C. § 102(e) as being anticipated by Rosenthal et al.

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

As note above, it is Applicants position that the priority documents do support the present claims. As a result, Rosenthal et al, which at best has a 102(e) date of June 26, 2000, is not effective prior art, as the present claims have an effective filing date of at least November 19, 1999.

Thus, Applicants request withdrawal of the Examiner's rejection.

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In paragraph 8, on page 8 of the Office Action, the Examiner rejects Claims 1-9, 11-15 and 17-23 under 35 U.S.C. § 102(b) as being anticipated by Lyman et al.

Specifically, the Examiner states that Lyman et al teaches the use of flt3-ligand in pharmaceutical compositions, and that such can be used in methods to stimulate T cell proliferation, as well as hemopoietic cells when treating patients with HIV.

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

Initially, Applicants note that the claims directed to treating a bacterial infection, i.e., Claims 10 and 16 have not been included in this rejection. For purposes of consistency Claim 2 should also not be included in this rejection.

Applicants respectfully submit that the Examiner's rejection is improper since the pending claims exclude HIV, which is specifically taught in Lyman et al.

It is clear that the claimed invention distinguishes over Lyman et al since Lyman et al does not teach or suggest treating patients afflicted with an infectious disease which is not HIV, and particularly treating subjects with a bacterial infection.

Thus, Applicants request withdrawal of the Examiner's rejection.

In view of the arguments set forth above, reexamination, reconsideration and allowance are respectfully requested.

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The Examiner is invited to contact the undersigned at the below-listed number on any matters which might arise.

Respectfully submitted,

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